

RECEIVED  
CENTRAL FAX CENTER

AUG 18 2006

Application No. 10/804,201  
Atty. Dkt. No. C261 1080.1 (51081.0008.9)**Remarks**

The claims as proposed to be amended are directed to isolated compounds, methods for treating *Vibrio cholerae* infections using the compounds, and processes for isolating the compounds. Newly added Claim 16 is directed to pharmaceutical compositions comprising the compound of Claim 1 and a pharmaceutically acceptable carrier.

Claim 1 has been amended to specify that the compound being claimed is an isolated compound, and Claim 2 has been converted from a compound claim specifying that the compound is effective against *Vibrio cholerae* into a claim directed to a method of treating a *Vibrio cholerae* infection. These amendments are clearly supported by the application as filed, and thus do not add new matter.

**Rejections under 35 U.S.C. 112, Second Paragraph**

Claims 1, 2, and 5 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite.

Claim 1 was rejected on the basis that the use of the phrases "extracted from" and "having biological activity," to describe a compound are unclear. In response, Claim 1 has been amended to refer to an isolated compound having a specific formula, and the language identified above has been deleted.

Claim 2 was rejected on the basis that it failed to limit Claim 1, as the intended use of a compound does not limit the compound itself. In response, Claim 2 has been amended to be in the form of a method of treatment claim, wherein a *Vibrio cholerae* infection is treated using the compound of Claim 1. It is believed that this amendment obviates the rejection.

Claim 5 was rejected on the basis that it included an improper Markush group. The claim has been amended to correct the language.

**Rejections under 35 U.S.C. 112, First Paragraph**

Claims 1-15 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has asserted that the specific mangrove plant in India, and the fungus extracted from the plant, which the claimed

- 5 -

WCSR 3408958v1

Application No. 10/804,201  
Atty. Dkt. No. C261 1080.1 (51081.0008.9)

compound is extracted, is not sufficiently described. The basis for the lack of sufficient description is apparently that the depository is not one recognized under the Budapest Treaty.

The depository used was the MTCC. This depository is recognized by the Budapest treaty, as evidenced by

[http://www.wipo.int/edocs/notdocs/en/budapest/treaty\\_budapest\\_204.html](http://www.wipo.int/edocs/notdocs/en/budapest/treaty_budapest_204.html), which states:

The Director General of the World Intellectual Property Organization (WIPO) presents his compliments to the Minister for Foreign Affairs and has the honor to notify him of the receipt from the Government of India, on August 6, 2002, of a written communication dated July 31, 2002, relating to the acquisition of the status of International Depository Authority by the Microbial Type Culture Centre and Gene Bank (MTCC), which states that this Depository Institution is located on the territory of India and includes a Declaration of Assurances to the effect that the Institution complies and will continue to comply with the requirements concerning the acquisition of the status of International Depository Authority specified in Article 6(2) of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977, and amended on September 26, 1980.

Pursuant to Article 7(1)(b), the Microbial Type Culture Centre and Gene Bank (MTCC) shall acquire the status of International Depository Authority under the Budapest Treaty on October 4, 2002, that is, on the sixtieth day succeeding the date of receipt of the communication by the Director General.

Accordingly, since the deposit was correctly made, Applicants respectfully request that this rejection be withdrawn.

Claims 3-14 were rejected under 35 U.S.C. 112, first paragraph, as non-enabled. The purported basis for the rejection is that the Examiner believes the specification only enabled for isolation of the claimed compound from specific fungi, which fungi are extracted from a specific leaves (from the mangrove plant). This rejection is respectfully traversed.

The specification, at page 6, states that in one embodiment, the compound is isolated from fungi, which was extracted from the leaves of a mangrove plant. However, it also states that in another embodiment, it was extracted from a fungi grown in culture (lines 19-

Application No. 10/804,201  
Atty. Dkt. No. C261 1080.1 (51081.0008.9)

24). Accordingly, the claims need not require that the fungi be extracted from the leaves of a specific plant.

Further, the Examiner has provided no evidence that the claimed method would not work with respect to other fungi than those actually deposited which might also include the claimed compound.

Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

#### Rejections under 35 U.S.C. 101

Claims 1 and 2 have been rejected as being directed to non-statutory subject matter. The basis for the rejection is that the compound is apparently not new, as it is found in mangrove plants. This rejection is respectfully traversed if applied to the amended claims.

Claims 1 and 2, as proposed to be amended, are directed to isolated forms of the compound (Claim 1) and methods of treatment of *Vibrio cholerae* infections using the compound. Applicants are unaware of prior art teaching the isolated compound or methods of treatment using the compound. It is well accepted patent law that an isolated compound, not previously known in the art, which isolated compound serves a useful purpose (in this case, antimicrobial activity), and methods of treatment using such a compound, are patentable subject matter.

The Examiner is respectfully requested to withdraw the rejections.

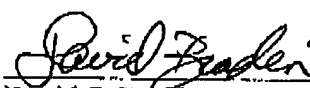
Application No. 10/804,201  
Atty. Dkt. No. C261 1080.1 (51081.0008.9)

**Conclusion**

It is believed that the claims are currently in condition for allowance, and such action is respectfully requested. No fee is believed to be due for this submission. Should a fee be required, the Director is authorized to charge any such fee to Womble Carlyle's Deposit Account No. 09-0528.

Respectfully submitted,

Date: August 18, 2006

  
David S. Bradin (Reg. No. 37,783)  
Womble, Carlyle, Sandridge & Rice  
P.O. Box 7037  
Atlanta, GA 30357-0037  
Office: 703-394-2216  
Fax: 703-790-2623

C261.1080.1 (51081.0008.9)